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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,705	02/11/2002	Dean Hughes	HO-P02368US0	4397

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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3732

DATE MAILED: 12/24/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,705

Applicant(s)

HUGHES ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afriat et al. (US 6,203,576) in view of Davidson (US 5,180,394).

Regarding claims 1-17 and 19-20, Afriat et al. disclose a knee joint prosthesis having a femoral component 1 with two condylar portions (5a, 5a), a cam 9 extending between the posterior portions of the condylar portions, a tibial component 2 configured to be implanted into a patient's tibia, and a tibial insert 3, made of an organic polymer such as high-density or "ultra-high molecular weight" polyethylene, having a proximal surface shaped to articulate against femoral component 1 wherein the distal surface of tibial insert 3 fits against the proximal surface of tibial component 2 and a central projecting rib or post 30 on the tibial insert 3 engages intercondylar cage or box 8 of femoral component 1 for posterior stabilization (Figure 1, col. 4, lines 19-67 and col. 5, lines 4-9 and lines 16-19).

Afriat et al. disclose the claimed invention except for a diffusion-hardened surface or coating on a portion of the cam.

Davidson teaches diffusion-bonded or "diffusion-hardened" coating of load bearing and non-load bearing surfaces of implants such as a knee joint prosthesis with blue-black or black zirconium oxide (col. 1, lines 14-35 and lines 61-68; col. 2, lines 1-8; col. 5, lines 11-26 and lines 47-55; col. 6, lines 51-68; and col. 7, lines 1-11 and lines 36-48). Davidson further teaches coatings of variable thickness (col. 8, lines 7-9 and lines 22-40; and col. 10, lines 18-21).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a diffusion-hardened coating on load-bearing and non load bearing contact surfaces of the knee joint prosthesis or implant of Afriat et al., as taught by Davidson, to minimize wear, reduce friction and improve fatigue properties of the implant.

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Further, regarding claims 5 and 13, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the prosthesis of the combination of Afriat et al. as modified by Davidson with a thicker coating on a load bearing surface (greater wear) than a non load bearing surface (lesser wear), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstein et al. (US 4,298,992) in view of Davidson (US 5,180,394).

Regarding claims 16-18, Burstein et al. disclose a knee joint prosthesis having a femoral component with two condylar portions (10,12), a cam or horizontal bar 16a extending between the posterior portions of the condylar portions and a tibial insert 30 configured to be implanted into a patient's tibia having a proximal surface shaped to articulate against femoral component when post 42 on the tibial insert engages the intercondylar recess or cage 16 of the femoral component (Figures 1-3 and 5-6, col. 3, lines 20-73 and col. 4, lines 1-29).

Burstein et al. disclose the claimed invention except for a diffusion-hardened surface or coating on a portion of the cam.

Davidson teaches diffusion-bonded or "diffusion-hardened" coating of load bearing and non-load bearing surfaces of implants such as a knee joint prosthesis with blue-black or black zirconium oxide (col. 1, lines 14-35 and lines 61-68; col. 2, lines 1-8; col. 5, lines 11-26 and lines 47-55; col. 6, lines 51-68; and col. 7, lines 1-11 and lines 36-48).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a diffusion-hardened coating on a contact surface (i.e., cam surface) of the knee joint prosthesis or implant of Burstein et al., as taught by Davidson, to minimize wear and improve the fatigue properties of the implant.

Response to Arguments

Applicant's arguments filed on November 26, 2003, in Paper No. 11, under "REMARKS," have been fully considered but are not persuasive with respect to claims 1-17 and 19-20.

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The inventions of references need not be physically combinable to render obvious an applicant's invention. In re Sneed, 710 F. 2d 1544, 218 USPQ 385, 389 (Fed. Cir. 1983). The test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference but rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413 208 USPQ 871 (CCPA 1981).

In the instant case, Davidson teaches coating surfaces of prostheses "contact zones" that bear against surfaces subject to high rates of wear, i.e., load bearing surfaces or "impact zones", for wear reduction or added strength (col. 1, lines 1-24). The horizontal cam extending between the intercondylar portions of a knee prosthesis is one example of a contact surface subject to high rates of wear.

Davidson also teaches coating of non-load bearing surfaces of an orthopedic implant for preventing corrosion of the implant and improving the fatigue properties of the implant (col. 1, lines 25-35). Obviousness is not determined on the basis of purpose alone. In re Graf, 343 F.2d 774, 777, 145 USPQ 197, 199 (CCPA 1965). It is sufficient if the prior art clearly suggests doing what applicants have done, although the underlying explanation of exactly why this should be done, other than to obtain the expected superior beneficial results is not taught or suggested in the cited references. In re Gershon, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967). As long as there is some suggestion/motivation within the prior art to make the modification or combination it does not have to be the same as the applicant's.

Allowable Subject Matter

The indicated allowability of claim 18 is withdrawn in view of the newly discovered reference(s) to Burstein et al. (US 4,298,992). The Examiner apologizes for any inconvenience caused to the Applicants.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anuadha Ramana*
December 21, 2003

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER